

WSA 2004 Proposed Project

Project Name:	N01459 - TES Follow-up Study	
Purpose:	1. Determine how many adult smokers participating in the TES have spontaneously switched to cigarettes with lower or higher tar yield (FTC method). 2. If more than 20 adult smokers can be identified as mentioned under Purpose 1 determine their exposure to cigarette smoke constituents using the same biomarkers of exposure and biologically effective dose as in the TES. 3. Compare biomarkers of exposure and biologically effective dose before and after switching.	
Reason for Doing this Work:	<input checked="" type="checkbox"/> Guidance <input type="checkbox"/> Evaluation <input type="checkbox"/> Product Design <input type="checkbox"/> Short Term <input checked="" type="checkbox"/> Long Term 	
Initiative and sub-initiative: (Check all areas that apply)	<div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> <input type="checkbox"/> Determinants of Exposure <ul style="list-style-type: none"> <input type="checkbox"/> Addiction <input type="checkbox"/> Ammonia <input checked="" type="checkbox"/> Understanding Product Toxicity vs Product Design <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Exposure <input type="checkbox"/> Carbon <input type="checkbox"/> Menthol <input type="checkbox"/> Low Tar <input type="checkbox"/> ETS <input type="checkbox"/> Specific Compounds </div> <div style="width: 48%;"> <input type="checkbox"/> Evaluation Framework Non-Clinical <ul style="list-style-type: none"> <input type="checkbox"/> Cancer <input type="checkbox"/> COPD <input type="checkbox"/> CVD <input type="checkbox"/> Molecular Biology <input type="checkbox"/> All Disease </div> </div> <div style="margin-top: 10px;"> <input type="checkbox"/> Evaluation Framework Clinical <ul style="list-style-type: none"> <input type="checkbox"/> Cancer <input type="checkbox"/> COPD <input type="checkbox"/> CVD <input type="checkbox"/> Molecular Biology <input type="checkbox"/> All Disease </div>	

Project Leader: Jan Oey

Functional Area: Clinical Evaluation

Prioritization: ☒ Critical ☐ Priority ☐ Secondary ☐ Low

Milestones:	Target Start Date	Original Finish Date	Previous Finish Date	Current Finish Date	Status
Design follow-up questionnaire	N/A	04/30/03	04/30/03	12/16/03	Completed
IRB approval	N/A	06/30/03	06/30/03	12/22/03	Completed
Follow-up contacts by call center	N/A	08/30/03	08/30/03	01/01/04	Ongoing
Completion of follow-up contact	N/A	09/30/04	09/30/04	04/30/04	On Schedule
Report follow-up questionnaire	N/A	05/31/04	05/31/04	05/31/04	Planned
Prepare protocol for follow-up investigations	N/A	06/30/04	06/30/04	02/15/04	Ongoing
Define study logistics with CRO	N/A	07/30/04	07/30/04	04/30/04	Planned
Contract with CRO	N/A	9/30/04	9/30/04	06/30/04	Planned
Protocol and IC approval by IRB	N/A	10/30/05	10/30/05	08/30/05	Planned
Start recruitment and collection of bio-samples	N/A	11/30/04	11/30/04	09/30/04	Planned
Collection of bio-samples completed	N/A	10/31/04	10/31/04	11/31/04	Planned
Bio-analysis completed	N/A	12/31/04	12/31/04	01/31/05	Planned
Data analysis completed	N/A	04/30/05	04/30/05	05/31/05	Planned
Draft report	N/A	10/31/05	10/31/05	08/31/05	Planned
Final Report	N/A	12/31/05	12/31/05	11/31/05	Planned

Internal Resource Allocation (WSA, PMRL, PMI)
(Man Hours)

Jan Oey: 100; Candace Adams: 20; Bettie Nelson: 50; Barb Zedler: 100;
Hans Roethig: 20; Robin Kinser: 50

External Resource Allocation (other PMUSA, external vendors)
(Man Hours)

TO BE FILLED OUT BY WSA MANAGEMENT

☐ Approved as Written